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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/933,366	08/20/2001	Sandra M. Sims	3523/2/US	4928

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EXAMINER

DELACROIX MUIRHEI, CYBILLE

ART UNIT PAPER NUMBER

1614

DATE MAILED: 12/31/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/933,366

Applicant(s)

SIMS, SANDRA M.

Examiner

Cybill Delacroix-Muirheid

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 September 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

1. Claims 1-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barbachyn et al., 5, 688,792 and in view of Bartroli et al., 5,646,294.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Amendment

The following is responsive to Applicant's amendment received Sep. 3, 2002.

No claims are cancelled. No new claims are added. Claims 1-30 are currently pending.

The previous claims rejection under 35 USC 112, paragraph 2, set forth in paragraph 1 of the office action mailed March 29, 2002 **is withdrawn** in view of Applicant's amendment and the remarks contained therein.

3. The declaration under 37 CFR 1.132 filed Sep. 3, 2002 is insufficient to overcome the rejection of claims 1-30 based upon 35 USC 103(a) as set forth in the last Office action because of reasons set forth hereinbelow.

Applicant's arguments traversing the previous rejection under 35 USC 103(a) set forth in paragraphs 2-4 of the office action mailed March 29, 2002 have been considered but are not found to be persuasive.

Said rejection is maintained essentially for the reason given previously in the office action mailed March 29, 2002 with the following additional comment:

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It is Applicant's position that Barbachyn and Bartroli do not fairly suggest to one of ordinary skill in the art the claimed invention. Specifically Applicant argues that the azole antifungals of Bartroli and the oxazolidinone compounds of Barbachyn are so different in size structure, lipophilicity, pKa and functionality that one of ordinary skill in the art would reasonably expect the cyclodextrins disclosed as solubilizing agents for the azole antifungals of Bartroli to be effective solubilizing agents for the oxazolidinone compounds of Barbachyn. Applicant submits a declaration in which Applicant describes the important structure of cyclodextrins and that hydrophobic interaction is an important factor for the incorporation of molecules within the interior of the cyclodextrins. The declaration then describes and compares the differences in size, molecular weight, hydrophobicity and basicity of the azole antifungals solubilized by cyclodextrins in the teachings of Bartroli and the oxazolidinone compounds of Barbachyn (see paragraphs 8-12 of the declaration). Applicant concludes that because of the numerous differences between the class of compounds, i.e. the azole antifungals and oxazolidinone, that one would not expect the cyclodextrins which solubilize the azole antifungals of Bartroli to also be capable of solubilizing the oxazolidinone compounds of Barbachyn. As stated at paragraph 13, one would not expect oxazolidinone compounds to be solubilized by cyclodextrins "merely because the same can be said of the azole antifungals."

Said arguments have been considered but, respectfully, are not found to be persuasive.

It is the Examiner's position that Bartroli et al. discloses to one of ordinary skill in the art that cyclodextrins are known solubilizing agents. In view of such a teaching, one of ordinary skill in

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the art would reasonably expect cyclodextrins to solubilize the oxazolidinone compounds of Barbachyn. Chemical compounds are always going to differ in their chemical properties and the prior art does not establish a limit on the type of compounds and their respective properties which may be solubilized by cyclodextrins. Moreover, it is not clear how the statements in Applicant's declaration serve to evidence unexpected results. For example, in paragraph 9 of the declaration, Applicant states that linezolid, which is embraced by the claimed invention, has a molecular weight of 337.35, whereas the molecular weights of the compounds in Bartoli are 484.42 and 480.39. Therefore, given the difference in molecular weight, one would not expect cyclodextrins to solubilize linezolid. However, the compounds of Bartoli have a much larger molecular weight than linezolid and yet they are capable of being solubilized by cyclodextrins. Therefore, absent evidence to the contrary, it would be logical to conclude that cyclodextrins would also be capable of solubilizing a much smaller compound such as linezolid.

Applicant's declaration is well noted; however, it does not clearly convey the unexpected nature of the claimed invention nor does it seem to effectively argue that the prior art teaches away from the claimed invention. The Examiner respectfully maintains that in view of Bartoli et al., modification of the compositions of Barbachyn to include cyclodextrins would have been motivated by the reasoned expectation of enhancing the solubility of the oxazolidinone compounds in the injectable formulations of Barbachyn et al., thereby producing a pharmaceutical composition that will be effectively delivered to the patient undergoing treatment.

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The rejection is respectfully maintained.

Information Disclosure Statement

4. The information disclosure statement filed Sep. 3, 2002 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

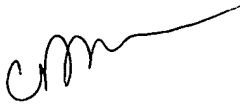
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cybille Delacroix-Muirheid whose telephone number is (703) 306-3227. The examiner can normally be reached on Tue-Fri from 8:30 to 6:00. The examiner can also be reached on alternate Mondays.

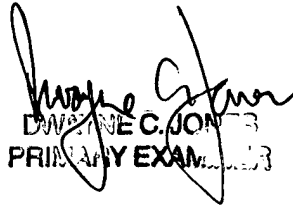
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

CDM



Dec. 30, 2002



DWAYNE C. JONES
PRIMARY EXAMINER